User's Manual

multiCare®

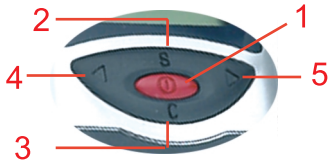
In-Vitro-Diagnostic aid for self testing

METER

1. DISPLAY
2. NAVIGATOR
3. STRIP HOLDER
4. PC CONNECTION
5. TEMPERATURE SENSOR

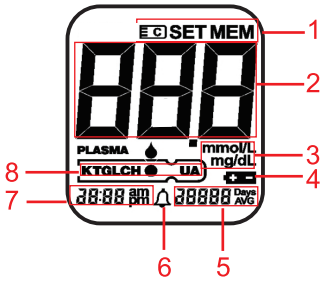
NAVIGATOR

1. ON/OFF
2. SETTING
3. MEMORY DELETING
4. LEFT ARROW
5. RIGHT ARROW



DISPLAY

1. METER'S MODE
2. RESULT AND DATA-CHIP NUMBER
3. UNIT OF MEASUREMENT
4. BATTERY
5. DATE AND AVERAGE OF RESULTS
6. ALARM
7. TIMES
8. TEST PARAMETER



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Introduction

Thank you for choosing multiCare. In this manual there are all the information for the correct use of the instrument. It is very important to carefully read them.

What is multiCare?

multiCare is a system that measures the concentration of glucose, cholesterol and triglycerides in the whole blood.
The multiparameter technology allows to measure, using only the multiCare instrument, different parameters by simply changing the type of strips and by using the correct data-chip for each parameter.

General information on the multiCare line

The multiCare line includes everything that is needed for daily check ups of the desired parameters:

- multiCare meter
- multiCare strips
- lancing device
- sterile lancets
- multiCare control solution
- multiCare data manager software

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Turning ON the instrument for the first time

When you turn on the meter for the first time, check if date, time and unit of measurement are correct before performing the test.
When you replace or remove the batteries, it is necessary to set the time, the hour and the date to perform the test (see pag. 31).

The instrument requires inserting of date, time and unit of measurement as OBLIGATORY settings.

This means that, if these settings are not done, the instrument will require the missing information and it is not able to perform any measurement.

It is very important to insert date, time and unit of measurement to have a correct memorization of the results and to have the signal at strips' expiring.
It is necessary to set winter and summer time as well as the addition of February 29th for leap years.

Every time that the batteries are replaced, the Obligatory settings of date, time and unit of measurement should be repeated.

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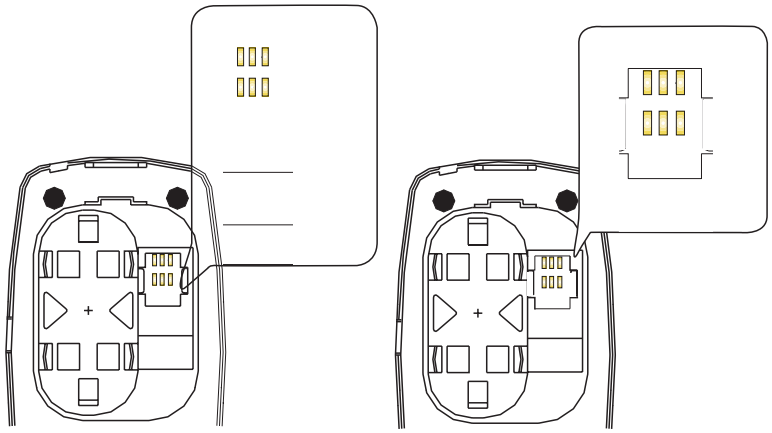
Carrying out the measurement

It is necessary to insert the data-chip contained in the correspondent strip pack in order to perform the desaired measurement.

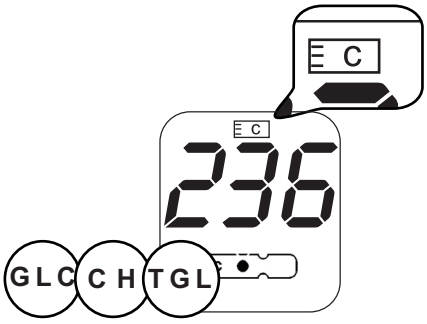
How to insert the data-chip

- Open the back cover of the instrument to uncover the housing of the data-chip.
- Insert the data-chip following the design.
- Close the cover and turn ON the instrument.



When the instrument is turned ON the display will show:

- A three digit number that is specific to the lot of strips **(data-chip number).**
- The symbol of the parameter (GLC for glucose, CH for cholesterol, TGL for triglycerides).
- An icon E C indicating that the data-chip is inserted in the instrument.



WARNING!
Every time a new package of strips of the same parameter is used or of a different parameter, remove the old data-chip and insert the data-chip contained in the new package. If this procedure is not followed, the results will be wrong.

When the data-chip is inserted, the display will show three digit number that should correspond to the one printed on the label of the strip's vial. If not, it means that you are using the wrong data-chip and the strips that you are using do not belong to that batch number.

Check always that the colour of the data-chip and the parameter symbol displayed on the instrument correspond to the parameter that you would measure.

GLC CH TGL

How to obtain a drop of blood

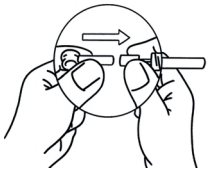
To carry out a measurement with the multiCare instrument, it is necessary to draw a drop of capillary blood from the fingertip following the procedure below:

- Wash hands with hot water to increase the circulation of the blood in the fingers. This will ease up the procedure.

- Dry hands thoroughly.
- Make sure that the finger to be pricked is completely dry.
- Prepare the lancing device contained in the multiCare kit by inserting the sterile needle.

Use a new undamaged needle for each blood sample and use the lancing device always on the same person.

- Unscrew the calotte of the lancing device turning it anti-clockwise while holding its body firmly.
- Insert a new needle until it stops in the support of the lancing device.



Before inserting, make sure that the needle and its protecting cover is undamaged. Only an undamaged protecting cover will guarantee that the needle is sterile.

- After inserting, carefully remove the protection cover from the needle while holding firmly the needle with the index and thumb.
- Keep the protecion cover so that it can be used to close and safely seal the needle after use.

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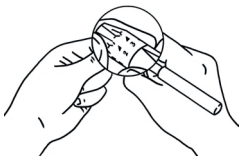
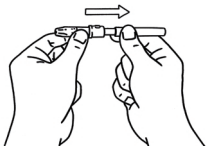
Carefully tighten the calotte of the lancing device on the lancing device.

Attention!
Avoid touching the tip of the needle!

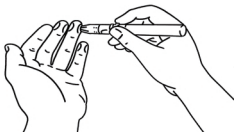


- By turning the calotte it is possible to adjust the depth of the needle.

Setting on 1 is appropriate for a particularly delicate skin, like children's, while setting on 5 is more suitable for thick skin. When using the lancing device for the first time select a setting in-between (position 3). After using, it will be possible to find the correct setting.



- Push the handle of the lancing device backwards until it stops. The lancing device is now loaded.

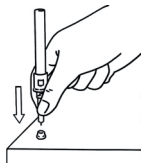


- To obtain a drop of blood, place the lancing device delicately against the side of the fingertip and then push the button. If the blood is not enough, squeeze the finger with the other hand to increase the blood flow.

WARNING!
To perfrom measurement with cholesterol or triglycerides strips it is necessary to apply an abundant drop of blood, at least 10µl.
For the glucose measurement it is sufficient to apply 3 µl of whole blood.

To avoid that the skin becomes hard, prick the finger in different areas or change finger tip for each test.

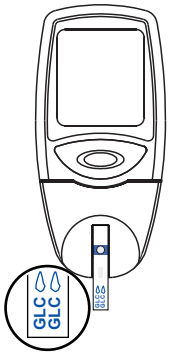
Removing a used needle:



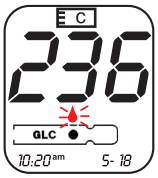
- Unscrew the calotte of the lancing device again.
- Press the lancing device with the needle at the opening of the protection cover of the needle.
- Remove the needle using the thumb and index.

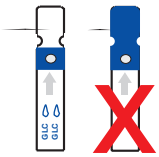
- Once the protection has been inserted, the needle can be disposed of with domestic rubbish. If the protecting cover of the needle is not available, make sure it is disposed of in appropriate vials.

How to perform the test



- Take a strip from the vial and then close it immediately to protect the other strips from humidity and light.
- **Insert the strip in the reading device of the instrument from the side showing the printed initials of the parameter at the top and push the strip until a click is heard.**
- If the strip is inserted correctly, a symbol showing a drop of blood appears on the display after about one and a half seconds.



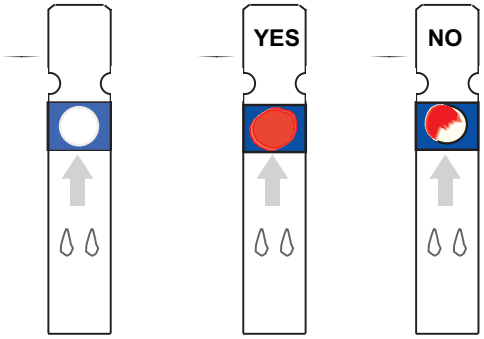


Using the lancing device, take a drop of blood from the fingertip following the procedure described at page 10.

- Do not use the first drop of blood, place the second drop over the circular white area.

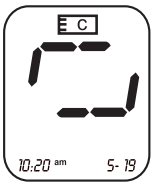
In case of cholesterol and triglycerides measurement, it is necessary to apply a big drop of blood (at least 10 µl).

The drop must saturate the reactive area completely.



It is possible to apply the blood when the strip is inserted in the multiCare instrument or it can be applied on the strip after pulling it out. The measurement will not be affected if the reactive area is briefly touched with the fingertip.

The moving segments on the display indicate that the measurement is in progress. The results of the measurements will be shown after a few seconds The measured value can be shown in mg/dl or in mmol/l (to change unit of measurement follow the instructions on page 17).



NOTE

If the results obtained do not correspond to the well being of the user, proceed with a check up of the multiCare instrument according to the procedure on page 18 and contact your physician.

If extreme results are obtained, too high (Hi) or too low (Lo), contact your physician immediately.

When the measuring is finished, it is possible to turn OFF the multiCare instrument. The instrument will shut down automatically after one minute and half if not used for other operations.

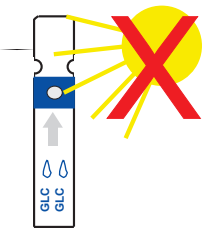
The measured value, along with date and time, will be saved in position 1 in the memory of the instrument. The values previously measured will be saved in positions 2, 3 etc. starting from the most recent. How to recall from the memory a measured value and how to erase memorized values is described on page 24 and 23.

The strips and other used material (except the instrument) can be disposed of with domestic rubbish.
In a laboratory and in a hospital, the procedures of biological safety must be followed when handling potentially infected material. After use, all of this material must be deposited in an appropriate container.

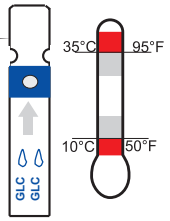
To avoid infections clean the instrument regularly and dispose of the used strips in a way that there is no risk of infections for other people.

The multiCare strips

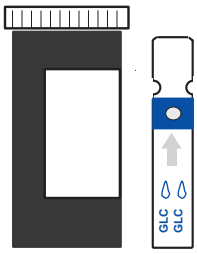
The correct use of the multiCare strips is very important for obtaining accurate results. Therefore it is important to keep in mind the following:



- The strips are sensitive to light and humidity: keep the strips only in their original vial.
- Protect the vial from direct sunlight and keep at a temperature between 10 and 35°C (50-95° F).



- Use the strips immediately after removing from the vial and close the vial immediately with its cap.
- The strips must not be used after the expiry date.
- When first opening, write the date on the vial: the strips must be used within 90 days after the vial has been opened.
- Do not use strips that are damaged.
- Tears, scratches, colour changes etc. give wrong results.
- Carefully read the instructions contained in the package of strips.
- Take measurements only with original multiCare strips.



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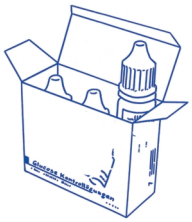
Checking the working of the multiCare



It is possible to check the working of the multiCare instrument using the multiCare control solutions. The control solutions can be obtained as a separate accessory through specialized retailers.
The control solution is applied on the strip just like blood.

When testing is done with the control solution, the obtained result must be within the interval as shown on the label of the strip's vial.
In this way, it is possible to learn how to use the multiCare properly and at the same time, check if it is working. Write the date of opening on the vial when the solution is opened for the first time.

The control solution must be used within 90 days from first opening, if the expiry date is valid.

When to carry out a working check up using the control solutions:

- When suspecting a possible defect of the multiCare instrument.
- When suspecting the possibility of a malfunction or wrong measurement.

Note

- Use only multiCare control solutions.
- Check the expiry date printed on each vial. Do not use the control solutions if expired.
- Use the control solutions within 90 days after first opening.
- Keep the control solutions at room temperature (10-35 °C - 50-95 °F).
- Do not use the control solutions to clean the instrument.
- Do not drink the control solutions and keep them away from children.
- The results obtained with the control solutions must be deleted in order to avoid alterations of the results' average (see page 21 on how to delete a value from the memory and for the average results).

Further instructions can be found in the package of the control solutions.

General Settings

After turning ON the instrument with key, by pressing S key you will enter in the setting mode and in the upper part of the display will appear the symbol SET and the date will blink.

Modification of the obligatory settings

It is possible to modify the following settings:

date - visualisation of the date - year - time visualisation of the time - unit of measurement

as described below:

- Select the desired setting by pressing the S key.
- To modify the selected setting, use the left or right arrow.
- Press the S key to confirm the modification and to select the next setting.
- To exit from the setting mode, press the key.

Setting the average of results

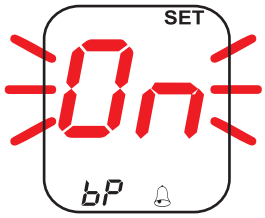
The multiCare instrument can show the average of the results over one, two, three or four weeks.
This function is important for glucose test to understand if the glucose concentration is under control.

- Turn ON the instrument.
- Press the S key until 0 starts blinking and the "days AVG" appears on the display.
- Press the right or left arrows to select 7, 14, 21 or 28 days.
- Press key to confirm the setting.

Setting the acoustic signal

The multiCare is set in such a way that an acoustic signal can be heard (“beep”):

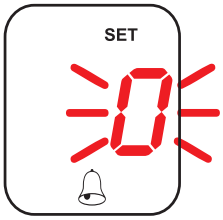
- When a strip is inserted.
- When the segments are visualized on the display.
- When the measured value is displayed.
- When data-chip is inserted if the instrument is turned on.
- When an error message is dispalyed.

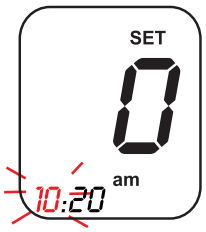


To enable or able the acoustic signal:

- Turn the instrument ON.
- Press the S key until BP appears on the display.
- By pushing one of the arrow keys, select the acoustic signal ON enabled or OFF disabled, then confirm with the key.

Setting the alarms





It is possible to set up four different alarms to remember when the measurements must be taken during the day. It is possible to set four different alarms for four different times (ex. in the morning before breakfast, after lunch, before bedtime and so on).

To set the alarm follow the procedure described below:

- Press the S key until “0” blinks on the display.
- Press one of the arrows to select the alarm number to be enabled (0, 1, 2 or 3).
- Press the S key again to select the hour and minutes.
- By pressing the S key again, it is possible to set the time of the corresponding alarm.

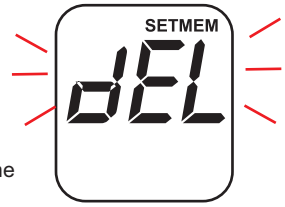
For the other alarms following the procedure described above.

By pushing the key we exit the Settings Mode and the settings are confirmed.

Deleting the results from the memory

It is possible to cancel one result or all of the memorized results.

Deleting all of the memorized results:



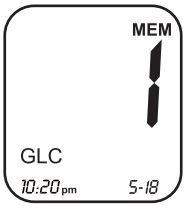
- Turn the instrument ON.
- Press the S key until “DEL” starts blinking on the display.
- Press key C: 'CLr' appears on the display.

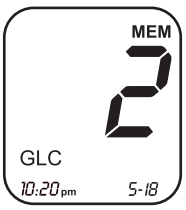
- Press key to confirm.

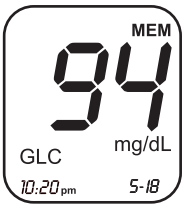
To delete only one value please follow the instruction indicated at page 21.

Every result obtained with the control solutions must be deleted, otherwise it will be included in the calculation for the average.

Recalling results and the average of the results from the memory







The multiCare instrument can memorize 250 results. Each result is memorized with:

- Time and date
- Parameter symbol (ex. GLC)
- Unit of measurement (mg/dl or mmol/l)
- The MEM symbol on the top of the display

To recall the results, just press the right arrow after turning ON the instrument without a strip inserted. Number 1 will be visualized (the last result obtained) and when the arrow is released, the result appears. By pressing the same arrow again, number 2 will be visualized and when it is released the corresponding result appears. If the other arrow is pressed it is possible to see result 1. By keeping one of the arrows pressed, a memorized value will be visualized every second.

If the average of the results has been set, when one of the arrows is pressed after turning ON the instrument, the first number visualized will be the average of the results. By pushing the same arrow again, number 1 will be visualized and when it is released the corresponding value.

How to cancel one value from the memory

To cancel only one value from the memory follow the procedure described below.

- Turn ON the instrument.
- Recall result to be deleted from the memory by using the left or right arrow.
- Press the C key to cancel value.

Enabling data transfer to a computer

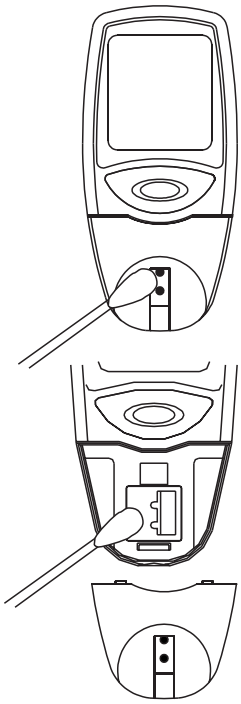
The multiCare system offers the possibility to transfer the measured values memorized in the memory of the instrument to a computer and read them with an analysis software and the aid of a cable.
The cable and the software are part of the multiCare Data Manager that can be bought as an accessory through specialized retailers.

Procedure:

- Install the software according to its instructions.
- Insert the serial port of the cable in the computer and the connector to the instrument.
- Press and release ⏻ key. “PC” will appear on the display of the instrument.
- Install the software to receive information from the instrument.
- After the data has been transferred, it is possible to turn OFF the instrument with the ⏻ key and remove the cable from it.

Detailed information can be found in the multiCare Data Manager manual.

Care and maintenance



It is important to carefully clean the multiCare instrument at least once a week. It is also necessary to immediately clean the plastic support of the reader or the optics if contaminated with blood or other material (debris, dust etc.).

- Use only wet tissue to clean the instrument.
- Do not soak the instrument in cleaning agents.
- Do not place under running water.
- After cleaning the plastic support of the reader, dry without scratching.
- It is possible to remove the front cover of the instrument to clean the glass surface of the optics.
- After cleaning, perform a working check up with the control solutions.

For taking measurements on different people, like in a hospital for example, clean the instrument after every measurement with a solution 70% alcohol before proceeding with the next measurement.

Preservation and measuring conditions

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To ensure the accuracy of each measurement, it is important to meet some conditions. The measurement with multiCare is possible within a temperature interval of 5 to 45 °C (41-113 °F).

At a temperature above 45 °C (113 °F) and below 5 °C (41 °F), error E01 will be shown on the display. The multiCare instrument must not be kept at temperatures below -25 °C (-75 °F) or above 60 °C (140 °F).

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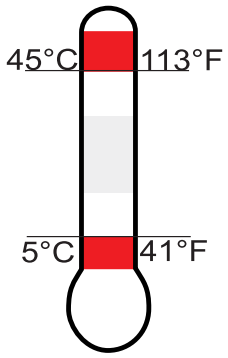


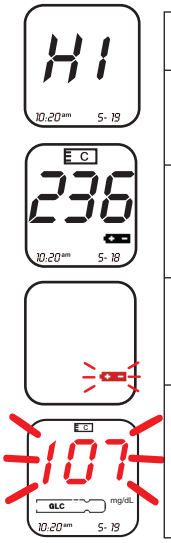
Note
If the instrument is too cold or too hot (ex. after being in a car at very low or high temperatures), allow it to cool down or to heat up slowly at room temperature.

multiCare®

Error Messages

	Error message	Problem	Solution
	E01	The temperature is lower than 5°C (41°F) or higher than 45°C (113°F).	Place the instrument in an area with temperature between 5°C(41°F) and 45°C (113°F) and wait for the instrument to equilibrate with the external temperature, before performing the measurement.
	E02	The strip is used or the reactive area is coloured.	Use a new strip to perform the measurement.
	E02	The strip is not correctly inserted.	Remove and insert the strip again, checking that it is plan on the plastic support of the instrument.
	E02	The blood was applied on the strip before waiting for the drop blinking on the display.	Take a new strip, insert it in the instrument and, only after visualized blinking drop on the display, apply the blood on the strip.
	E02	The plastic support or the reading window are dirty.	Pull out the plastic support where you insert the strip and clean the glass window using only water. Dry the glass without scratch it. Do not use solvents or soap. Insert the plastic support and repeat the test.
	E03	The strip is removed from the meter without applying the drop of blood.	Switch off the meter by ON/OFF button. Insert the strip again and apply the blood on the strip without remove the strip from the strip holder
	E04	The strip that you are using does not correspond to the parameter of the data-chip.	Remove the data-chip and use the one corresponding to the strip that you want to use and check that the parameter symbol on the display is the same of the one printed on the strip.

Error message	Problem	Solution
E04	The strip is inserted upside-down.	Insert the strip again and be careful that the parameter symbol printed on the strip is on the upper part of the strip.
E05	Data-chip error.	Remove the data-chip and insert it again. If E05 still remains, contact Multicare customer Service.
E06	The blood is not enough.	Repeat the test and apply more blood.
E07	The data-chip is not inserted.	Insert the data-chip corresponding to the strips that you want to use.
LO	The result is lower than the limit of that parameter (see also instruction for use of the strips).	If the result does not correspond to the personal sensations, repeat the test. If LO is obtained again, contact your physician for additional information.
LO	In the case of parameters cholesterol and triglycerides, where blood's quantity to be applied has to be abundant, it is possible to obtain LO if the quantity of blood is under the limit of enough volume.	Repeat the test with a big quantity of blood. If LO is obtained again, contact your physician for additional information.



Error message	Problem	Solution
HI	Value is higher than the limit of reading of that parameter.	Contact immediately your physician and repeat the test in an hospital.
	The batteries are almost flat. It is possible to perform about 30 measurements.	Get new batteries.
	The batteries are flat.	Replace the batteries before taking a measurement.
	The result is discontinuous when the strip has expired.	Check expiry date of the strips and use new strips to perform the measurements. Blinking result is not saved in the memory.

Possible error reasons

First of all verify the following points:

- The obligatory settings has been properly followed (see page 5)?
- The data-chip number shown on the label of the strip's vial is corresponding to the one that appears on the display (see page 7)?
- Is the data-chip of the package corresponding to the parameter under control (see page 7)?
- The strip has been inserted on the correct side (see page 11)?
- The drop of blood is enough (see page 11)?
- The results of the measurement taken with the control solutions are within the reference interval printed on the label of the strip's vial (see page 15)?
- The instrument and the reading plastic support have been cleaned according to the instructions at page (see page 23)?

- The date of the control solutions and of the strips is expired (see page 14)?
- Have the strips been used over 90 days after the vial has been opened (see page 14)?
- Are the strips kept in their original vial (see page 14)?
- The strips have been exposed to extreme temperatures and/or humidity (see page 14)?
- Is the battery flat (see page 30)?

If the instrument after verifying the above points, does not work correctly, contact the multiCare Costumer Service by e-mail multicare@biosys.it or phone 0039 0575 984164.

Further information on how to use the multiCare System can be found on our site www.biosys.it

Substituting the batteries

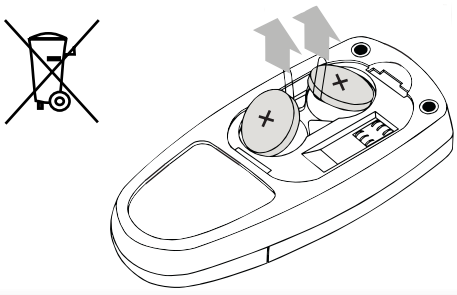
The multiCare instrument houses two lithium batteries 3V (type CR 2032). If the battery icon is blinking, the charge is low and the battery must be replaced before taking a measurement.

Note

Every time the battery is replaced or simply removed the time and date must be set again.
Always insert a new battery and not a used one.
Shut down the instrument before removing the battery. Check out the new battery to see if it is of the right type before placing.

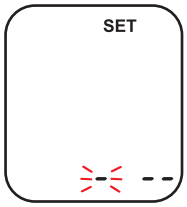
How to change the battery:

- Open the back panel of the instrument.
- Press the lever and remove the cover.
- Remove the battery by pulling the plastic ribbon.
- Place the new battery so that the type is readable. The positive side of the battery must be at the top.
- Close the back cover until a click is heard.
  Flat batteries can be disposed of trhough recycling centers.

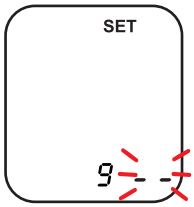


Obligatory Settings

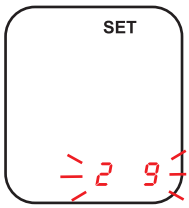
- The blinking line indicates the month. Select the month with the arrow keys left or right.
- Press ⏻ button to confirm.

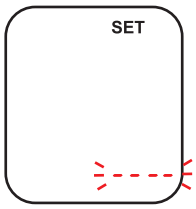


- The blinking two lines indicate the day. Select the day with the arrow keys left or right.
- Press ⏻ button to confirm.

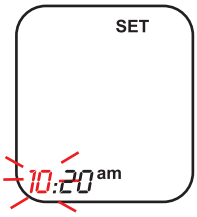


- The month and day blink together. With the arrow left or right, choose the preferred visualisation of the date configuration MM/DD (month-day) or configuration DD/MM (day-month).
- Press ⏻ button to confirm.





- The blinking four lines indicate the year. Select the year with the arrow keys left or right.
- Press ⏻ button to confirm.

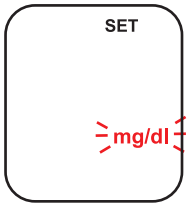


- The hour blinks. Select the hour using the arrow left or right.
- Press ⏻ button to confirm.

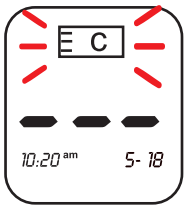
- The minutes blink. Select the minutes using the arrow left or right.
- Press ⏻ button to confirm.

- The complete time blinks and 12h appears on the display. Select the visualisation of the hour 12h or 24h using the arrow keys left or right.
- Press button to confirm.

- The unit of measurement mg/dl blinks on the display. Select the unit of measurement mg/dl or mmol/l using the arrow keys left or right.
- Press button to confirm.



After confirmed the selected unit of measurement on the display will blink the symbol of the data-chip E C: the instrument requires data-chip to perform the measurement.



Performance

Measurement range:	25-500 mg/dl (1.4-28 mmol/l) glucose 130-400 mg/dl (3.3 - 10.2 mmol/l) cholesterol 50-500 mg/dl (0.56-5.6 mmol/l) triglycerides
Power source:	2x3V lithium button cell, type CR 2032. The battery can be used for approx. 1 year with 3 measurements per day (approx. 1000 measurements)
Dimensions:	105 mm - length 20,5 mm - height 52 mm - width
Weight:	65 g (incl. battery)
Display:	LCD
Climatic operating conditions Temperature limits:	5 to 45 °C (41 °F to 113 °F)
Humidity limits:	0% to 90% relative humidity (non-condensing)
Memory capacity:	250 measured values with time and date
Interface for data processing:	Connecting cable
Special requirements for electromagnetic radiation:	The CE mark on the device indicates that it complies with the requirements of the EC directives 89/336/EEC relating to electro-magnetic compatibility 73/23/EEC for electrical equipment intended for use in areas of specific voltage levels
Hint for Healthcare Professionals:	The appropriate legal provisions apply or the use of multiCare. The accuracy of the instrument should be checked after 3 years
Waste management disposal when the meter is unusable:	Please refer to local updated regulation!

multiCare®

Symbols used on the packaging

Follow instructions

IVD

In-Vitro-Diagnosticum

Use until...

LOT

Batch number...

Store at temperatures between

3 V ⎓
2xCR 2032

3V direct current and battery type

CE
0123

CE mark

Do not dispose the instrument in the urban waste. Perfom a separated collecting specific for Electric and Electronic waste or give the instrument to the distributor when you buy a new one or when you want to sobstitute it.
Please refere to local update regulation.

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Information on the conditions of guarantee

Biochemical Systems International Srl grants to the customer that the instrument will be free of material defects and manufacturer handling for 3 years starting from the purchasing date. During such period, Biochemical Systems International Srl should replace the defected instrument with an equivalent version or the same model after verifying the defect.

Such warranty is subject to exception and limitation as described below. The warranty is limited to the replacement due to defects in some parts and handling. Instruments that present defects due to damages caused from improper use, alteration, negligence, technical assistance performed from not authorised personnel, accident, abuse or by using strips which are different from multiCare will not be replaced.

Biochemical Systems International Srl reserves the right to apply technical modifications to the instrument multiCare without the obligation to insert such specification to those products already introduced in the market.

Any other warranty will be granted for this product unless the replacement option described above.
Every responsibility for special, indirect or consequential damages is excluded.

Customer Service

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Customer Service

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